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11/20/98

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-05

October 30, 1998

Luis H. Rodriguez, President
Blue Fin International, Inc.
7531 Northwest 52nd Street
Miami, Florida 33166

Dear Mr. Rodriguez:

On September 15-16, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish importing and repacking facility. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing the fish products being imported, repacked, and stored by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

Your current written HACCP plan to control a potential histamine hazard in scombroid fish species handled by your firm fails to specify a critical limit for maximum temperature allowed at the receiving critical control point. We would consider a critical limit of 40° F to be appropriate to ensure that products received were handled during transit in a manner to prevent temperature abuse and reduce the risk of histamine formation [21 CFR 123.6(c)(3)].

Failure to follow the monitoring procedure specified in your HACCP plan for temperature measurements of fish at the receiving critical control point. Temperature measurements of fish at receiving are not being performed and monitoring record data is not being maintained [21 CFR 123.6(c)(7)].

Failure to maintain adequate sanitation control records [21 CFR 123.11(c)] that document the monitoring and corrections during receiving, repacking, and storage of all sanitation conditions specified in the regulations, for example, proper labeling, storage, and use of toxic compounds, and control of employee health conditions [21 CFR 123.11(b)].

For your operation as an importer, failure to have and implement written importer verification procedures [21 CFR 123.12(a)(2)] that include product specifications [21 CFR 123.12(a)(2)(i)] and at least one of the listed affirmative steps [21 CFR 123.12(a)(2)(ii)] to ensure that imported fish products you offer for sale were processed in accordance with the requirements of the HACCP regulation.

In addition, your HACCP plan specifies a critical limit of 50 ppm histamine at the receiving critical control point. However, you plan has no provisions for monitoring the presence of histamine or maintaining records. Laboratory analysis for histamine is an excellent way to verify that your HACCP procedures are working. Table #7-2 of the Fish and Fisheries Products Hazards & Controls Guide, Second Edition, Page 87, provides an example of how histamine analysis can be used for verification purposes.

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your importing, repacking, and storage facility. It is your responsibility to ensure that all fish products received, stored, and distributed by your firm are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any fish products received and stored by your firm until compliance with the seafood regulations is achieved.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Douglas D. Tolen
Director, Florida District